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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/808,558 | 03/14/2001 | Michael M. Becker | GP068-05.CN3 | 3920 |
| 21365 | 7590 | 08/12/2005 | EXAMINER | |
| GEN PROBE INCORPORATED 10210 GENETIC CENTER DRIVE SAN DIEGO, CA 92121 | | | CALAMITA, HEATHER | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | |
| DATE MAILED: 08/12/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|----------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/808,558 | | BECKER ET AL | |
| | Examiner | | Art Unit | |
| | Heather G. Calamita, Ph.D. | | 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 422-429, 431-433, 440-448, 450-459 and 461-479 is/are pending in the application.
- 4a) Of the above claim(s) 441-448, 450-459, 461-463, 465 and 473-479 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 422-428, 431-433, 440 and 466-472 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>06/06/2005</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 20, 2004, has been entered.

Status of the Application

2. Claims 422-429, 431-433, 440-448, 450-459, 461-479 are currently pending in the instant application. Claims 441-448, 450-459, 461-463, 465, 473-479 are withdrawn. Claims 422-429, 431-433, 440, 464 and 466-472 are currently under examination.

Claim Rejections - 35 USC § 112 (New Matter)

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 422-428, 431-433, 440 and 466-472 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection.

Claim 422-428, 431-433, 440 and 466-472 recite, "wherein the probe does not form a triple-

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stranded structure with the nucleic acid analyte under said nucleic acid conditions” however, the specification does not provide specific support for this recitation. The specification does not specifically disclose in an embodiment excluding the formation of a triple-stranded structure with the nucleic acid analyte.

Applicants assert support for this recitation appears in the specification at page 2 lines 15-18. However, the passages cited in the specification do not recite the language “wherein the probe does not form a triple-stranded structure with the nucleic acid analyte under said nucleic acid conditions” but rather the passage recites “hybrids usually consist of double-stranded duplexes, although triple-stranded structures are also known.” If Applicants traverse this rejection, it is suggested that Applicants point to, specifically, where there is support for the recitation of “wherein the probe does not form a triple-stranded structure with the nucleic acid analyte under said nucleic acid conditions.”

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 422-428, 431-433, 440 and 466-472 rejected under 35 U.S.C. 102(b) as being anticipated by Agrawal et al. (WO 94/01550).

Agrawal et al. teach (claim 422) a hybridization assay probe for use in determining the presence of a nucleic acid analyte in a sample, the probe comprising a detectable label and a first and second base regions capable of hybridizing to each other under nucleic acid assay conditions to form a hybrid containing at least one ribonucleotide modified to include a 2'-O-alkyl substitution to the ribofuranosyl moiety, wherein the probe forms a stable double-stranded hybrid with the nucleic acid analyte but not

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with a non-targeted nucleic acid under nucleic acid conditions, such that the nucleic acid analyte can be detected, and wherein the probe does not form a triple-stranded structure with the nucleic acid analyte under said nucleic acid assay conditions (see page 15, lines 1-30).

With regard to claim 423, Agrawal et al. teach the portion of the first base region includes a cluster of at least about 4 ribonucleotides modified to include a 2'-O-alkyl substitution to the ribofuranosyl moiety (see page 16, lines 24-36).

With regard to claim 424, Agrawal et al. teach at least one nucleotide which is not a ribonucleotide modified to include a 2'-O alkyl substitution to the ribofuranosyl moiety (see page 16, lines 24-36).

With regard to claims 425 and 426, Agrawal et al. teach ribonucleotides modified to include a 2'-O alkyl substitution to the ribofuranosyl moiety (see page 16, lines 24-36).

With regard to claim 427, Agrawal et al. teach the probe includes a conjugate molecule (see page 17, lines 1-12).

With regard to claim 428, Agrawal et al. teach the probe includes a conjugate molecule joined to the probe at a site located within the cluster of the first base region (see page 17, lines 1-12).

With regard to claim 429, Agrawal et al. teach the first and second base regions are contained within an oligonucleotide that is between 10 and 100 bases in length (see p. 15 line 30).

With regard to claim 431, Agrawal et al. teach the label comprises a fluorescent molecule (see p. 17 line 9).

With regard to claims 432 and 433, Agrawal et al. teach the nucleic acid analyte comprises RNA and ribosomal RNA (see page 10, lines 14-36).

With regard to claims 440, 467-472, Agrawal et al. teach the 2'-O-alkyl substitution to the ribofuranosyl moiety is a 2'-O-methyl substitution (see p. 16 lines 25-29).

With regard to claim 464, Agrawal et al. teach a target sequence contained within the nucleic acid analyte includes a double stranded region (see page 8, lines 23-35 and Figure 6).

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With regard to claim 466, Agrawal et al. teach the hybrid formed between the first and second base region is more stable than a hybrid formed between unmodified forms of the first and second base regions (see page 16, lines 24-36).

Since the structure of the claimed probe was disclosed by Agrawal et al., the claimed functions “for use in determining the presence of nucleic acid analyte in a sample” would have been an inherent property of the oligonucleotide taught by Agrawal. Note MPEP 2112.01 states in part “[w]here the claimed and prior art products are identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established.”

Response to Arguments

6. Applicant's arguments filed June 6, 2005, have been fully considered but they are not persuasive. With respect to the 102 (b) rejections Applicant argues Agrawal do not teach each and every element of the claimed probes, specifically Agrawal do not teach a label. However, Agrawal do teach a label (see p. 17 line 9). Agrawal teach acridine orange or ethidium both of which are fluorescent molecules used as labels. Agrawal do not refer to the molecules as labels however both acridine orange and ethidium meet the structural limitation of the claim. Agrawal therefore anticipates the claims.

Applicant's arguments with respect to the 103 (a) rejections have been considered but are moot in view of the new ground(s) of rejection.

Summary

7. No claims are allowable.

Correspondence

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is

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heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

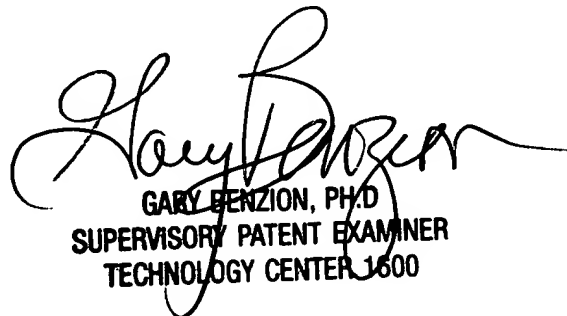
Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

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